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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,396	03/31/2004	Benjamin D. McDaniel	51992/AW/W112	9596

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	PAPER NUMBER
3739	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,396	MCDANIEL ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,11-15,17-22 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,11-15,17-22 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's amendments and comments, received June 4, 2007, have been fully considered by the examiner now of record. The following is a complete response to the June 4, 2007 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-4, 7, 13, 17-20, 22, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. (U.S. Pat. No. 6,117,101) in view of Abele (U.S. Pat. No. 5,860,974).

Regarding claim 1, Diederich et al. disclose a catheter comprising: an elongated catheter body 652 having proximal and distal ends and at least one lumen therethrough (Fig. 13); a three-dimensional ablation assembly 650 at or near the distal end of the catheter body, said assembly having a framework 651 defining a length and a circumference, the assembly movable into a collapsed configuration with a greater length and a lesser circumference and an expanded configuration with a lesser length and a greater circumference, the framework comprising a plurality of tensile members interwoven in a manner such that the length increases as the circumference decreases and vice versa (col. 26, ln. 38-44 and Fig. 13); said assembly also having a ribbon electrode extending along said circumference, said ribbon electrode adapted to move with said framework (col. 27, ln.12-25).

The claim differs from Diederich in calling for a tip electrode mounted at or near a distal end of the ablation assembly. Abele, however, teaches that it is obvious to use an analogous expandable cage electrode to ablate a heart chamber wall in order to correct arrhythmias (col. 1, ln. 12-15 and Figs. 24-25). Abele further teaches that it is advantageous to have a tip electrode mounted at a distal end 76 of such an ablation assembly 72 in order to sense cardiac signals to locate the target tissue to be ablated and/or to provide an additional ablation electrode (col. 7, ln. 35-45, col. 8, ln. 7-8, 58-64, and Figs. 13, 17, and 18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have mounted a tip electrode at the distal end of the ablation assembly of Diederich in view of the teaching of Abele in order to sense cardiac signals to locate the target tissue to be ablated and/or to provide an additional ablation electrode.

Regarding claim 2, Diederich further discloses that said framework of the assembly in the expanded configuration has a first circumference in a first section along its length and a different second circumference in a second section along its length (col. 26, ln. 38-44 and Fig. 13).

Regarding claim 3, Diederich further discloses an expander 653 attached at or near its end to distal ends of the tensile members 651 (col. 26, ln. 34-44 and Fig. 13) and extending through the catheter body (col. 26, ln. 26-35), the expander having a proximal end that extends out the proximal end of the catheter and having a lumen extending therethrough (col. 26, ln. 34-44 and Fig. 13), whereby, in use, the expander can be moved longitudinally relative to the catheter body 652 to expand and collapse

the ablation assembly. Since the expander 653 is used to expand the ablation assembly, it must inherently have a proximal end that extends out the proximal end of the catheter body so that the user can actuate it.

Regarding claim 4, Diederich further discloses that the expander 653 extends through at least a distal portion of the catheter body 652 (col. 26, In. 26-44 and Fig. 13). In addition, see the preceding rejection of claim 3.

Regarding claim 7, Diederich further discloses that the expander is moved proximally to actuate the assembly into the expanded configuration (Fig. 13).

Regarding claim 13, Diederich further discloses that the expander has a proximal end attached to a control handle. Since the expander is used to actuate the assembly expansion, the expander must inherently have a control handle to allow the user to actuate the expander.

Regarding claim 17, Diederich further discloses that the expander 653 is generally coaxial with the catheter body 652 (Fig. 13).

Regarding claim 18, Diederich further discloses that the expander 653 forms the axis of the assembly 650 (Fig. 13).

Regarding claim 19, Diederich further discloses that the assembly 650 comprises at least four tensile members 651 (Fig. 13).

Regarding claim 20, Diederich further discloses that each tensile member 651 comprises an internal flexible wire and a non-conductive covering over the flexible wire (col. 27, ln. 5-6 and Fig. 13).

Regarding claim 22, Diederich further discloses that the ribbon electrode is elastic (col. 27, ln. 12-25).

Regarding claim 31, the claim differs from Diederich in calling for a plurality of ribbon electrodes. It would have been obvious, however, to one of ordinary skill in the art at the time the invention was made to provide a plurality of ribbon electrodes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Further, Abele teaches a plurality of ribbon electrodes 40, 42 on an analogous expandable member in order to allow bipolar ablation (col. 3, ln. 29-32, col. 6, ln. 49-54 and Figs. 4-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plurality of ribbon electrodes in the device of Diederich in view of the teaching of Abele in order to allow bipolar ablation.

Claims 11-12, 14, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. ('101) in view of Abele ('974) and further in view of Webster, Jr. (U.S. Pat. No. 5,772,590).

Regarding claim 11, Diederich discloses that the expander comprises a tube (col. 26, ln. 34-36). The claim differs from Diederich et al. in calling for the expander to

comprise plastic tubing. Webster, Jr., however, teaches an expandable electrode catheter with an expander 56 comprising plastic tubing (col. 9, ln. 12-13 and Fig. 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the expander of Diederich et al. comprise plastic tubing in view of the teaching of Webster, Jr. because plastic is an obvious alternate material for constructing tubes that is well-known in the art.

Regarding claim 12, Diederich discloses that the expander comprises a tube (col. 26, ln. 34-36). The claim differs from Diederich et al. in calling for the expander to comprise braided plastic tubing. Webster, Jr., however, teaches an expandable electrode catheter with tube 7 comprising braided plastic tubing (col. 5, ln. 13-16 and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the expander of Diederich et al. comprise braided plastic tubing in view of the teaching of Webster, Jr. because braided plastic is an obvious alternate material for constructing tubes that is generally known in the art (pg. 14 of applicant's specification).

Regarding claim 14, the claim differs from Diederich et al. in calling for the control handle to comprise: a handle housing having proximal and distal ends, and a piston having a proximal end mounted in the distal end of the handle housing and a distal end fixedly attached to the proximal end of the catheter body; wherein the proximal end of the expander is fixedly attached, directly or indirectly, to the handle housing so that longitudinal movement of the piston relative to the handle housing results in longitudinal

movement of the expander relative to the catheter body to thereby expand and collapse the assembly.

Webster, Jr. ('590), however, teaches an expandable electrode catheter with a control handle 50 (Fig. 9) comprising the handle of U.$. Pat. No. 4,960,134 also to Webster, Jr. (incorporated by reference into Webster, Jr. '590).

With reference to Webster, Jr. ('134), the control handle 13 comprises: a handle housing 40 having proximal and distal ends, and a piston 46 having a proximal end mounted in the distal end of the handle housing and a distal end fixedly attached to the proximal end of the catheter body 11 (col. 4, ln. 45-49 and Fig. 4);

With reference to Webster, Jr. ('590), the control handle 50 comprises an expander 54, wherein the proximal end of the expander is fixedly attached, directly or indirectly, to the handle housing so that longitudinal movement of the piston relative to the handle housing results in longitudinal movement of the expander relative to the catheter body to thereby expand and collapse the assembly (col. 8, ln. 61 - col. 9, ln. 7 and Figs. 9-10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the control handle of Diederich et al. to comprise the control handle of Webster, Jr. ('590/'134) in view of Webster, Jr. ('590) as an obvious way to expand the tensile members of Diederich et al. that is known in the art.

Regarding claim 21, Diederich discloses that the internal flexible wire of each wire comprises a superelastic metal alloy, such as an alloy of nickel and titanium, or a combination of both (col. 26, ln. 63-65). The claim differs in calling for the internal flexible wire of each wire to comprise nitinol - a specific type of nickel and titanium alloy. Webster, Jr. ('590), however, teaches an expandable electrode catheter, wherein the tensile member wires comprise nitinol (col. 6, ln. 27-38). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the internal flexible wire of Diederich et al. from nitinol in view of the teaching of Webster, Jr. ('590) because nitinol is an obvious specific type of nickel and titanium alloy that is well-known in the art.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Abele ('974) in view of Webster, Jr. ('590) in view of Edwards et al. (U.S. Pat. No. 5,471,982) and further in view of Webster, Jr. (U.S. Pat. No. 6,183,463 B1).

Regarding claim 15, the claim differs from Diederich et al. in calling for the proximal end of the expander to extend outside the proximal end of the control handle and through a support tube.

Edwards et al. teach an expandable electrode catheter, wherein fluid is introduced to the point of ablation through the expander tube 240 to keep the electrodes free of tissue buildup and blood (col. 19, ln. 50 - col. 20, ln. 2 and Figs. 12 and 26).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included fluid introduction through the expander tube of Diederich et al. in view of the teaching of Edwards et al. to keep the electrodes free of tissue buildup and blood.

Webster, Jr. ('463)teaches an electrode catheter, comprising the piston control handle of Webster, Jr. ('590/'134) with a fluid introduction tube 88 that starts at the distal electrode end and then extends outside the proximal end of the control handle and through a support tube 91 (col. 8, ln. 18-26, col. 9, ln. 7-26, and Figs. 1-4). Fluid is introduced through the luer hub 90 (col. 8, ln. 33-39 and Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the proximal end of the expander/fluid introduction tube of Diederich et al. in view of Edwards et al. to extend outside the proximal end of the control handle of Diederich et al. in view of Webster, Jr. ('590/'134) and through a support tube further in view of the teaching of Webster, Jr. ('463) as an obvious alternate way of introducing fluid that is known in the art for use with the control handle of Webster, Jr. ('590/'134).

Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich ('101) and Abele ('974) and further in view of an alternate embodiment of Diederich ('101).

Regarding claim 32, Diederich discloses a catheter comprising:

an elongated catheter body 652 having proximal and distal ends and at least one lumen therethrough (Fig. 13); and a three-dimensional ablation assembly 650 at or near the distal end of the catheter body, said assembly having a framework 651 defining a length and a circumference, the assembly movable into a collapsed configuration with a greater length and a lesser circumference and an expanded configuration with a lesser length and a greater circumference, the framework comprising a plurality of tensile members interwoven in a manner such that the length increases as the circumference decreases and vice versa (col. 26, ln. 38-44 and Fig. 13), said assembly also having a ribbon electrode extending along said circumference, said ribbon electrode adapted to move with said framework (col. 27, ln. 12-25).

The claim differs from Diederich in calling for the framework to be sufficiently flexible that the diameter need not be constant along the length and the length need not be constant along the circumference so that the framework can conform to an interior volume of a nonuniformly-shaped tubular region. In an alternate embodiment, however, Diederich teaches a cage framework 352 that is radially compliant and in accordance with claim 32 in order to allow the ablation member to conform to a pulmonary vein ostium (col. 18, ln. 45-58 and Fig. 7b). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the cage framework of Diederich radially compliant and in accordance with claim 32 in view of the teaching of an alternate embodiment of Diederich in order to allow the ablation member to conform to a pulmonary vein ostium.

Regarding claim 33, the claim differs from Diederich in calling for a plurality of ribbon electrodes. It would have been obvious, however, to one of ordinary skill in the art at the time the invention was made to provide a plurality of ribbon electrodes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.,* 193 USPQ 8.

Response to Arguments

Applicant's arguments filed June 4, 2007 have been fully considered but they are not persuasive.

Applicant has amended claim 1 to recite a framework that is "adapted to readily conform to a nonuniformly shaped tubular region". Similar recitation is found in independent claim 32. Applicant contends that the Diederich and Abele references fail to disclose such a feather. The examiner disagrees.

There is no structural limitation associated with the above language, nor is there any explicit definition of what is meant by "readily conform". The examiner maintains that the Diederich device, which includes a wire basket-type framework comprised of several small-diameter wires, would inherently meet the limitation of "adapted to readily conform to a nonuniformly shaped tubular region". The individual wires of the of the Diederich device are of a very small diameter and would clearly conform to any desired shape of a passageway. For example, if the device were located within a blood vessel with a deposit on one side of the passageway, clearly the wire framework would conform to that luminal shape and would not compress the deposit as a rigid angioplasty might. Applicant's argument that there is no disclosure in Diederich is not

tenable since this feature is clearly and inherently present in such a device. That Diederich does not disclose the use of the device in a nonuniform tubular region does not preclude its use in such a region, nor does it limit the manner in which the structure would inherently react (e.g. conform to a shape) given the size and flexibility of the ablation assembly. That Diederich does not show or disclose the inherent flexibility of the ablation assembly does not mean it does not fit the broad recitation found in claims 1 and 32. The examiner maintains that the small diameter wires of the Diederich embodiment would clearly be very resilient, as is necessary for its expansion and contraction, and would inherently conform to a shape of a lumen when deployed. Applicant has proffered no explanation as to why the Diederich device would be incapable of meeting such a limitation, and has only argued that Diederich does not expressly disclose such an intended use.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
January 11, 2009